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## 5. 510(k) Summary or 510(k) Statement

*V-RASER Diode Laser System 510k Summary*

HOYA ConBio™
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| Submitter: | HOYA ConBio, Inc.<br>47733 Fremont Blvd.<br>Fremont, California 94538<br>Phone: 510-445-4500<br>Fax: 510-445-4550 |
| Contact: | Mr. Jim Green<br>Vice President of Engineering |
| Date Summary Prepared: | November 21, 2007 |
| Device Trade Name: | V-RASER Diode Laser System |
| Common Name: | Dermatology Laser System |
| Classification Name: | Instrument, surgical, powered, laser<br>79-GEX |
| Classification Code: | 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide.<br>(2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon. |
| Equivalent Device: | Diodent Micro 980 (K063384), Iridex Varilite (K041930), |
| Device Description: | The V-RASER Diode System is a modified Diodent Micro 980. It will use similar specifications (laser medium, excitation method, fiber optic beam delivery, electrical requirements, physical specifications) as the Diodent Micro 980. The laser source of this device is a solid-state Gallium Aluminum Arsenide (GaAlAs) semiconductor diode. It produces invisible laser energy at the 980-nanometer wavelength. The delivery system consists of removable flexible HCS (hard clad silica) optical treatment fiber |

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| | assembly connected to a lightweight, hand piece that has two different size end pieces (tips) to adjust the laser beam to specific spot sizes. Activation occurs when the operator enables the laser by a key switch, enters the Ready Mode and presses the footswitch. Releasing the footswitch suspends laser treatment. A color LCD and touch-screen display panel allows the operator to adjust or set the laser output level. The laser operates in a pulsed mode and will have a removable stainless steel end piece for establishing the proper focal length for the treatment. The hand piece will be manually attached (i.e., screwed on) to a connector to the fiber assembly. The spot size will be selected on the control panel and the software will calculate the treatment fluence accordingly. |
| Intended Use: | Incision, excision, ablation, vaporization and coagulation of soft tissue. Indicated for the treatment of vascular lesions. |
| Comparison: | The V-RASER Diode Laser System is comparable to its predicate and parent device in terms of its indications for use, technical specifications, operating performance features, and general design features. |
| Nonclinical Performance Data: | None |
| Clinical Performance Data: | None |
| Additional Information: | None requested at this time. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 14 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HOYA ConBio, Inc.
% Liza Burns and Associates
Ms. Liza Burns
Regulatory/Clinical Consultant
19722 Westview Drive
Twain Harte, California 95383

Re: K073332
Trade/Device Name: V-RASER Diode Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 21, 2007
Received: November 21, 2007

Dear Ms. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known): _____

Device Name: V-RASER Diode Laser System

Intended Use:The V-Raser is intended for Incision, excision, ablation, vaporization and coagulation of soft tissue.

Specific Indications: Treatment of vascular lesions.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073332